

REMARKS

Reconsideration of this application is respectfully requested.

Applicant thanks Examiner Chernyshev and Examiner Ulm for the courtesy of the Interview held on September 26, 2003. In the Interview, the undersigned provided a copy of the 11 Exhibits filed with the May 19, 2003, Amendment, and explained their relevance to the utility of the claimed invention. During the Interview, the undersigned argued that the claimed nucleic acids fulfill the utility requirement of 35 U.S.C. § 101. Applicant was advised that the asserted utility of IL-1 delta as a marker for a specific region of human chromosome 2 is not considered a specific and substantial utility by the Office.

Claims 63, 64, and 68-78 have been canceled without prejudice or disclaimer. Applicant expressly reserves the right to pursue the subject matter of these claims in a continuation application. Applicant has amended the specification to remove browser-executable code, insert references to SEQ ID NOs, and replace the previous sequence listing with a substitute sequence listing.

Applicant has amended claim 62 to recite more stringent conditions. The amendment is supported throughout the specification, for example, on page 12, lines 24-25.

Applicant provides herewith a paper copy and a computer-readable form of the substitute sequence listing. The paper copy of the substitute sequence listing and the computer-readable form are the same. The amendment adds no new matter.

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Sequence Compliance

The Office indicated that the previous sequence listing did not include all of the sequences present in the application. Applicant has replaced the previous sequence listing with a substitute sequence listing and has amended the specification to insert references to SEQ ID NOs.

Specification

The Office objected to the specification for containing embedded hyperlinks and/or other form of browser-executable code. Applicant has amended the specification such that references to internet sites are no longer browser-executable. Accordingly, Applicant respectfully requests withdrawal of the objection.

Claim Objections

The Office objected to the claim 64 for reciting "hybridizes either strand." Claim 64 has been canceled. Thus, the objection is moot.

Rejections under 35 U.S.C. § 101

Claims 58-78 were rejected under 35 U.S.C. § 101 for allegedly lacking utility. The Office discarded Applicant's asserted utilities for the claimed nucleic acids as a chromosomal marker as "not a substantial or specific utility." (*Id.* at 5.)

Applicant traverses the rejection. As supported by the accompanying Declaration under 37 C.F.R. § 1.132 of John E. Sims, Applicant's asserted utility is specific and substantial.

**The claimed nucleic acids can be used to distinguish conditions
in which the human IL-1 delta gene is rearranged or deleted**

All of Applicant's claimed nucleic acids have the property of being capable of specifically hybridizing to a specific region on chromosome 2. This property results from

the specific localization of the human IL-1 delta gene on chromosome 2. (Specification at 37, lines 2-9.) Based on this specific localization, Applicant's claimed nucleic acids have certain utilities, which Applicant expressly asserted in the specification, and which are sufficient to fulfill 35 U.S.C. § 101. For example, Applicant asserted that the claimed nucleic acids can be used to distinguish conditions in which the human IL-1 delta gene is rearranged or deleted. (Specification at 37, lines 24-30.) This utility is a specific and substantial utility.

Applicant points out that this is a utility of the claimed IL-1 delta nucleic acids themselves, which is independent of any encoded polypeptide. To focus the Office on this particular utility of the claimed nucleic acids, above and beyond the utility of encoded polypeptide, Applicant has canceled claims 63, 64, and 68-78, which recite an encoded polypeptide. Applicant will focus this response on the evidence supporting that this particular utility is a specific and substantial utility for the claimed IL-1 delta nucleic acids.

Applicant's asserted utility is specific

Applicant's asserted utility that IL-1 delta nucleic acids can be used to distinguish conditions in which the human IL-1 delta gene is rearranged or deleted is **specific**. (Declaration at ¶¶4-10.) The specificity of this utility arises from the specific location of the human IL-1 delta gene on chromosome 2. (Declaration at ¶¶7-9.) In fact, the Office admits that IL-1 delta DNA can specifically detect chromosome 2. (Paper No. 21 at 5: "DNA encoding IL-1 delta is not the only DNA that can be used to specifically identify chromosome 2.") It is apparent from this statement that the Office does not dispute the specificity of Applicant's claimed nucleic acids for chromosome 2.

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The fact that other DNAs may have a similar specificity to IL-1 delta nucleic acids is immaterial. The U.S. Court of Appeals for the Federal Circuit has stated: "An invention need not be the best or the only way to accomplish a certain result, and it need only be useful to some extent and in certain applications." *Carl Zeiss Stiftung v. Renishaw plc*, 20 U.S.P.Q.2d 1094, 1100 (1991). Therefore, Applicant's claimed nucleic acids do not need to be the best or only way to distinguish conditions in which the human IL-1 delta gene is rearranged or deleted. Rather, Applicant's claimed nucleic acids need only be useful to some extent and in certain applications. Applicant's claimed nucleic acids fulfill this requirement.

A specific utility is one "that is specific to the subject matter claimed" in contrast to "a general utility that would be applicable to the broad class of the invention." M.P.E.P. § 2107.01 at p. 2100-32, col. 1. All polynucleotides would not be useful for the asserted utility. (Declaration at ¶9.) For example, all polynucleotides could not distinguish conditions in which the human IL-1 delta gene is rearranged or deleted. Thus, Applicant's asserted utility is specific to the claimed subject matter.

Applicant's asserted utility is substantial

Applicant's asserted utility that IL-1 delta nucleic acids can be used to distinguish conditions in which the human IL-1 delta gene is rearranged or deleted is **substantial**. (Declaration at ¶¶4-6 and 11-20.) Applicant localized the human IL-1 delta gene to chromosome 2q11-12. (Declaration at ¶6.) As the specification asserts, human IL-1 delta nucleic acids can be used "to distinguish conditions in which this marker is rearranged or deleted" "using well-known techniques." (Specification at 37, lines 27-30.)

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One well-known technique that is specifically described in the specification is “*in situ* hybridization to chromosome spreads.” (*Id.* at 37, lines 7-8.) Thus, Applicant’s specification indicates that human IL-1 delta nucleic acids can be used for *in situ* hybridization to chromosome spreads to distinguish conditions in which the human IL-1 delta gene is rearranged or deleted. (Declaration at ¶6.) Since, the human IL-1 delta gene is localized to 2q11-12, the skilled artisan would have understood that IL-1 delta nucleic acids could be used to distinguish conditions associated with rearrangements or deletions of 2q11-12. (Declaration at ¶7.) This utility is substantial.

The substantial nature of this asserted utility is supported by objective evidence. (Declaration at ¶¶4-6 and 11-20.) In 1984, a paper was published describing a condition associated with rearrangements or deletions of 2q11-12. Mu et al., *Journal of Medical Genetics*, 1984, 21:57-71. (Declaration at ¶12.) Mu et al. examined a patient with various abnormalities, and found an abnormal proximal long arm of chromosome 2. *Id.* at 57, Summary. (*Id.*) The patient in Mu et al. was suffering from numerous physical abnormalities. (*Id.*) The authors determined that there was a tandem duplication of 2q11.2-q14.2. (*Id.*)

Based on Mu et al, the skilled artisan would have understood that IL-1 delta nucleic acids could be used for *in situ* hybridization of chromosome spreads from this patient to distinguish rearrangements or deletions of the human IL-1 delta gene. (Declaration at ¶13.) That is, IL-1 delta nucleic acids could be used to determine the presence of normal chromosome 2 sequences on one of the chromosomes and for characterizing the duplicated region of the abnormal chromosome. (*Id.* at ¶13-14.) This is a “real world use.” (*Id.* at ¶18.)

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A substantial utility is one "that defines a 'real world' use." M.P.E.P. § 2107.01 at 2100-32, col. 2. Since Applicant's utility defines a "real world use," Applicant's utility is a substantial utility.

In addition, "any reasonable use that an applicant has identified for the invention that can be viewed as providing a public benefit should be accepted as sufficient, at least with regard to defining a 'substantial' utility." M.P.E.P. § 2107.01 at 2100-33, col.

1. Applicant's use of IL-1 delta nucleic acids to distinguish rearrangements or deletions of the human IL-1 delta gene in patients should be viewed as providing a public benefit since the patient in Wu et al., as well as patients with a similar chromosomal and resultant physical abnormalities, would benefit from diagnosis using Applicant's claimed nucleic acids. (Declaration at ¶¶19-20.) Such diagnosis would identify the cause of the physical abnormalities exhibited by the patient, and would rule out other causes of the abnormalities.

Moreover, Applicant's utility can be practiced without any need for any additional research. (Declaration at ¶11.) Contrary to the Examiner's assertion, the instant situation is not directly analogous to *Brenner v. Manson*. Unlike the situation in *Brenner*, Applicant's claimed nucleic acids are not simply "alleged to be potentially useful." Rather, Applicant's specification asserts a specific, substantial, and credible utility for the claimed nucleic acids. Accordingly, the Examiner's reliance on *Brenner* is misplaced.

The substantial nature of this asserted utility is supported by additional objective evidence. For example, in 1998, a paper was published describing a condition associated with rearrangements or deletions of 2q11-12. Glass et al., *Journal of*

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Medical Genetics, 1998, 35:319-322. (Declaration at ¶15.) Glass et al. examined two patients (mother and child) with various abnormalities, and found an abnormal chromosome 2. (*Id.*) The patients in Glass et al were suffering from numerous physical abnormalities. (*Id.*)

Using fluorescence *in situ* hybridization (FISH), the authors determined that the patients had a proximal 2q trisomy (2q11.2-q21.1). (*Id.*) FISH showed an insertion of chromosome 2-derived material into the middle of the short arm of chromosome 8. (*Id.*)

Based on Glass et al, the skilled artisan would have understood that IL-1 delta nucleic acids could be used for *in situ* hybridization of chromosome spreads from these patients to distinguish rearrangements or deletions of the human IL-1 delta gene. (Declaration at ¶16.) That is, IL-1 delta nucleic acids could be used to determine the presence of normal chromosome 2 sequences and for characterizing the insertion of material derived from chromosome 2 into chromosome 8 described by Glass et al. (Declaration at ¶¶17-18.) This is a "real world use" providing a benefit to real world patients. (Declaration at ¶18.)

The evidence of record shows that, as Applicant asserted in the specification, the claimed nucleic acids can be used to distinguish conditions in which the human IL-1 delta gene is rearranged or deleted. (Declaration at ¶¶7, 10-11, 13-14, and 17-20.) The Office has provided no evidence to the contrary. In view of the evidence of record, it is indisputable that Applicant's claimed nucleic acids are useful at least "to some extent and in certain applications," which is sufficient to fulfill the utility requirement of 35 U.S.C. § 101. See *Carl Zeiss Stiftung v. Renishaw plc*, 20 U.S.P.Q.2d at 1100. Accordingly, Applicant respectfully requests withdrawal of the rejection.

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Rejections under 35 U.S.C. § 112, first paragraph

Claims 58-78 were rejected under 35 U.S.C. § 112, first paragraph, for allegedly not having either a specific and substantial asserted utility or a well established utility for the same reasons set forth for the rejections under 35 U.S.C. § 101.

Applicant traverses the rejection. For the reasons detailed above, the skilled artisan would understand how to use the claimed invention. Accordingly, Applicant respectfully requests withdrawal of the rejection.

Claims 64-71 and 73-78 were rejected under 35 U.S.C. § 112, first paragraph, because the specification allegedly does not reasonably provide enablement for any nucleic acid molecule encoding a fragment of the polypeptide of SEQ ID NO:4 that has the ability to bind to cells expressing an IL-1 delta receptor.

Applicant traverses the rejection for the reasons set forth in the Amendment filed May 19, 2003. However, as discussed above, Applicant has canceled claims 64 and 68-78. Claims 65-67 have been amended to depend from claim 62. Accordingly, this rejection is moot.

Claims 60-61, 64-71, and 73-78 were rejected under 35 U.S.C. § 112, first paragraph, as allegedly containing subject matter that was not described in the specification in such a way as to reasonably convey to the skilled artisan that the inventor had possession of the claimed invention at the time the application was filed. It is the Office's position that the specification only describes a nucleic acid of SEQ ID NO:3 and an encoded protein having the amino acid of SEQ ID NO:4, and fails to describe any other nucleic acid that lacks SEQ ID NO:3 and encodes a protein that has the activities possessed by IL-1 delta polypeptide.

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Applicant traverses the rejection. As Applicant previously pointed out in the Amendment filed May 19, 2003, claims 60 and 61 encompass nucleic acids without regard to the ability of any encoded polypeptide to bind to cells expressing an IL-1 delta receptor. Consequently, none of the Office's reasons for lack of an adequate written description is relevant to claims 60 and 61. Accordingly, Applicant respectfully requests withdrawal of the rejection as it pertains to claims 60 and 61.

Moreover, as discussed above, Applicant has canceled claims 64, 68-71 and 73-78. Claims 65-67 have been amended to depend from claim 62. Accordingly, this aspect of rejection is moot.

Claims 63-71 were rejected under 35 U.S.C. § 112, first paragraph, because the specification allegedly does not reasonably provide enablement for a nucleic acid molecule that hybridizes to the coding sequence of SEQ ID NO:3 and encodes a polypeptide that binds to cells expressing an IL-1 delta receptor. The Office contends that there is no knowledge existing in the art or guidance in the specification for making a nucleic acid that encodes a specific polypeptide from an antisense strand.

Applicant traverses the rejection for the reasons set forth in the Amendment filed May 19, 2003. Moreover, as discussed above, Applicant has canceled claims 63, 64, 68-71 and 73-78. Claims 65-67 have been amended to depend from claim 62. Accordingly, this rejection is moot.

Rejections under 35 U.S.C. § 112, second paragraph

Claims 58 and 70-71 were rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter that applicant regards as the invention.

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The Office alleges that claim 58 is vague and indefinite in the recitation of "consisting essentially of." Applicant has amended claim 58 to recite "consisting of." Accordingly, Applicant respectfully requests withdrawal of the rejection.

The Office also alleges that claims 70-71 are vague and ambiguous because it is not clear what polypeptide is intended by the claims. As discussed above, Applicant has canceled claims 70 and 71. Thus, this rejection is moot.

Applicant submits that this application is in condition for allowance. If the Examiner should disagree, she is invited to contact the undersigned to discuss any remaining issues.

If there is any fee due in connection with the filing of this paper, please charge the fee to our Deposit Account No. 06-0916.

Respectfully submitted,

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Date: December 19, 2003

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